K081762

Curbell Electronics, Inc.
www.curbellelectronics.com

510(k) Summary

1. Company: Curbell Electronics, Inc.
20 Centre Drive
Orchard Park, NY 14127
Telephone: 716-667-3377 x419
Fax:716-667-1390

AUG 27 2008

2. Contact: Kevin Walls
Regulatory Insight, Inc.
5401 S. Cottonwood Ct.
Greenwood Village, Colorado 80121
Telephone: 720-962-5412
Fax: 720-962-5413
Email: kevin@reginsight.com

3. Date Prepared: June 18, 2008

4. Trade Name: Curbell Patient Monitoring Cables

5. Common Name: Patient Monitoring Cables

6. Classification Name: Patient Transducer and Electrode Cable (including connector) (21CFR870.2900, Product Code DSA)

7. Predicate device: Merit Cables, Inc. 510(k) K942321

8. Device description: Curbell Patient Monitoring Cables and Lead Wires.

9. Indications for Use: Curbell patient cables are used to connect electrodes and/or sensors placed at the appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by a healthcare professional.

10. Technological characteristics to predicate device: Curbell Patient Monitoring Cables are substantially equivalent in safety and effectives to the predicate device, Merit Industries, Inc. (K942321), as demonstrated in the following table:

	Curbell Patient Cables	Merit Industries, Inc.
510(k) number	N/A	K942321
Intended use	Used to connect electrodes, catheters, and/or sensors placed at the appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by a healthcare professional.	Used to connect electrodes, catheters, and/or sensors placed at the appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by a healthcare professional.
Usage	Reusable	Reusable

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Anatomical site	Attached to sensors placed at specified locations as required by the patient monitor. Examples include Left arm, Right arm, Chest, Left leg & Right leg.	Attached to sensors placed at specified locations as required by the patient monitor. Examples include Left arm, Right arm, Chest, Left leg & Right leg.
Design	Shielded and unshielded patient leadwires and shielded patient trunk cables with electrode connectors including snap, pinch, & Sure Lock.	Shielded and unshielded patient leadwires and shielded patient trunk cables with electrode connectors including snap, pinch, & Sure Lock.
Connectors	Electrode connectors - snap, pinch, & Sure Lock.	Electrode connectors - snap & pinch
Cable and lead wire length	Trunk Cable lengths include - 10 ft Leadwire lengths from 18" to 51"	Trunk Cable lengths include - 7 to 20 ft., Leadwire lengths from 18" to 120"
Wire material	Shielded & Unshielded Copper with Polyurethane Jacket	Shielded & Unshielded Copper with PVC or Polyurethane Jacket
Sterility	Non Sterile	Non Sterile
Electrical performance testing	Per AAMI - EC 53	Per AAMI - EC 53
Electrical safety testing	• Dielectric withstand per AAMI - EC 53 • Insulation resistance per AAMI - EC 53 • Termination resistance per AAMI - EC 53	• Dielectric withstand per AAMI - EC 53 • Insulation resistance per AAMI - EC 53 • Termination resistance per AAMI - EC 53
Connector retention force	Per AAMI - EC 53	Per AAMI - EC 53
Environmental safety	Cables are RoHS complainant	Cables are RoHS compliant
Meets ANSI/ AAMI standard	ANSI/AAMI EC53:1995 (revised 2001)	ANSI/AAMI EC53:1995 (revised 2001)

11. Nonclinical performance data:

Curbell Patient Monitoring Cables have been assessed to the following FDA performance standard and national and international standards:

- 21 CFR 898
- IEC 60601-1, Subclause 56.3(c)
- ANSI/AAMI EC53:1995(R)2001

12. Clinical data: None

13. Conclusion from nonclinical testing: The summary above illustrates that there are no new questions or differences in the safety and effectiveness of the Curbell Patient Monitoring Cables to the predicate device.

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Anatomical site	Attached to sensors placed at specified locations as required by the patient monitor. Examples include Left arm, Right arm, Chest, Left leg & Right leg.	Attached to sensors placed at specified locations as required by the patient monitor. Examples include Left arm, Right arm, Chest, Left leg & Right leg.
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Electrical safety testing	• Dielectric withstand per AAMI - EC 53 • Insulation resistance per AAMI - EC 53 • Termination resistance per AAMI - EC 53	• Dielectric withstand per AAMI - EC 53 • Insulation resistance per AAMI - EC 53 • Termination resistance per AAMI - EC 53
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Curbell Electronics, Inc.
c/o Mr. Kevin Walls
Regulatory Insight Inc.
5401 S. Cottonwood Ct.
Greenwood Village, CO 80121

AUG 27 2008

Re: K081762
Trade/Device Name: Curbell Patient Monitoring Cables
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer and Electrode Cable (including connector)
Regulatory Class: Class II (two)
Product Code: DSA
Dated: August 18, 2008
Received: August 21, 2008

Dear Mr. Walls:

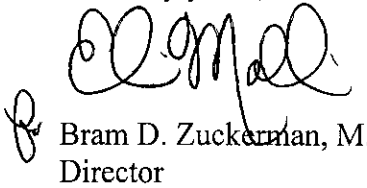
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081762

Device Names: Curbell Patient Monitoring Cables

Indications for Use: Curbell patient cables are used to connect electrodes and/or sensors placed at the appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by a healthcare professional.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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